

Atty Dkt. No.: PALO-004  
USSN: 10/748,976

**REMARKS**

In view of the following remarks, the Examiner is respectfully requested to withdraw the rejections and allow Claims 1-14 and 17-38; the only claims pending and under examination.

Claims 1 has been amended to include the subject matter of Claims 15 and 16. Accordingly, Claims 15 and 16 have been canceled.

Claims 12-14 and 21-38 have been withdrawn.

As no new matter has been added by the above amendments, the Examiner is respectfully requested to enter the above amendments.

**Rejection under 35 U.S.C. § 112, second paragraph**

In the Office Action, Claim 19 has been rejected under 35 U.S.C. § 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In making this rejection, the Examiner asserts that it is unclear how the method step recited in Claim 19 relates to the other method step of the parent claim.

The MPEP states that the statutory requirements for clarity are satisfied if the claims of an application when read in light of the specification, reasonably apprise one of skill in the art of what is being claimed.<sup>1</sup>

Claim 19 recites the following: The method of Claim 1, further comprising determining the ratio of Th-1 activity/Th-2 activity.

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<sup>1</sup> MPEP § 2173.05(a): "If the claims, read in light of the specification, reasonably apprise those skilled in the art both of the utilization and scope of the invention, and if the language is as precise as the subject matter permits, the statute (35 U.S.C. 112 second paragraph) demands no more."

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The Applicants submit that Claim 19 is fully described in the instant specification at para. [0020] and [0024]. As such, one of skill in the art would fully understand that Th1 and Th2 activity may be determined to indicate whether a fertility-favorable level of sympathetic activity is present in a subject and therefore, related to the method step of Claim 1.

In view of the foregoing discussion, the Applicants submit that the clarity requirements of 35 U.S.C. 112, second paragraph, have been met, and requests that this rejection may be withdrawn.

**Claim Rejections under 35 USC § 102(e)**

In the Office Action, Claims 1, 4, 7, 9, 10 and 20 were rejected under 35 U.S.C. §102(e) as being anticipated by Rezai (U.S. Patent Application NO. 2005/0065574). The Applicants note that Claim 15 is not included in this rejection. Without any intention to acquiesce to the correctness of this rejection, Claim 1 has been amended to recite the subject matter of Claim 15. Accordingly, the rejection of Claims 1, 4, 7, 9, 10 and 20 under 35 U.S.C. § 102(e) may be withdrawn.

**Claim Rejections under 35 USC § 103(a)**

Claims 2 and 3 have been rejected under 35 U.S.C.103(a) as being unpatentable over Rezai (U.S. Patent Application No. 2005/0065574) in view of Bothe Loncar et al. (U.S. Patent Application No. 2002/0188336). Since Claims 2 and 3 directly or indirectly depend on Claim 1, each of the rejected claims now includes the element of Claim 15, a claim not included in this rejection. Accordingly, rejection may be withdrawn.

Claims 5, 6 and 11 have been rejected under 35 U.S.C.103(a) as being unpatentable over Rezai (U.S. Patent Application No. 2005/0065574) in view of Whitehurst et al. (U.S. Patent No. 6,832,114). Since Claims 5, 6 and 11 directly or

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indirectly depend on Claim 1, each of the rejected claims now includes the element of Claim 15, a claim not included in this rejection. Accordingly, rejection may be withdrawn.

Claim 8 has been rejected under 35 U.S.C.103(a) as being unpatentable over Rezai (U.S. Patent Application No. 2005/0065574) in view of Mann et al. (U.S. Patent Application No. 2002/005761). Since Claim 8 indirectly depends on Claim 1, Claim 8 now includes the element of Claim 15, a claim not included in this rejection. Accordingly, rejection may be withdrawn.

Claims 15-18 have been rejected under 35 U.S.C.103(a) as being unpatentable over Rezai (U.S. Patent Application No. 2005/0065574) in view of Verrier et al. (U.S. Patent No. 5,437,285).

As amended, the elements of Claims 15 and 16 have been incorporated into Claim 1, as reviewed above, and Claims 15 and 16 have correspondingly been canceled.

Each of the pending claims now includes the elements of determining the sympathetic activity/parasympathetic activity ratio at least prior to a modulation and performing the modulation based on the determined ratio. These elements are simply not taught or suggested in the combined teaching of Rezai in view of Verrier.

Rezai is silent as to determining the sympathetic activity/parasympathetic activity ratio at least prior to a modulation and performing the modulation based on the determined ratio.

As such, the Examiner is relying on Verrier et al. to make up for the deficiency of Rezai.

In making the rejection, the Examiner specifically states that "it would have been obvious to one having ordinary skill in the art at the time the invention was made to

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modify Rezai's invention by determining the ratio of sympathetic activity to parasympathetic activity to sense the vulnerability of the organ innervated by the ANS" (Office Action, p. 6).

Verrier et al. discloses a method of assessing cardiac vulnerability by analyzing at least one of a beat-to-beat alternation in a T-wave of an ECG of a patient's heart. Verrier discloses that "the magnitude of the high frequency component of heart rate variability is indicative of parasympathetic activity" (col. 7, line 21). As such, Verrier simply teaches that when analyzing heart rate variability, parasympathetic activity corresponds to the magnitude of the high frequency component.

In contrast, amended Claim 1 now includes the subject matter of Claims 15 and 16 which recites the following:

A method of treating a female subject for a fertility condition comprising modulating at least a portion of the autonomic nervous system of said female subject to increase the sympathetic activity/parasympathetic activity ratio of said subject, in a manner effective to treat said female subject for said fertility condition, wherein said method further comprises determining said sympathetic activity/parasympathetic activity ratio at least prior to said modulation and performing said modulation of said at least one portion of the autonomic nervous system based on the determined sympathetic activity/parasympathetic activity ratio.

As such, the present methods include determining the sympathetic activity/parasympathetic activity ratio at least prior to said modulation and performing the modulation based on the determined sympathetic activity/parasympathetic activity ratio as well.

Nowhere in the disclosure does Verrier teach or suggest a method of actually determining the sympathetic activity/parasympathetic activity ratio at least prior to modulation and then performing the modulation based on the determined sympathetic

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activity/parasympathetic activity ratio, as presently claimed. As such, Verrier fails to make up for the deficiency of Rezai. Accordingly, this rejection may be withdrawn.

Claim 19 has been rejected under 35 U.S.C.103(a) as being unpatentable over Rezai (U.S. Patent Application No. 2005/0065574) in view of Khan et al. (U.S. Patent Application No.2002/0064501). Since Claim 19 directly depends on Claim 1, Claim 19 now includes the element of Claim 15, a claim not included in this rejection. Accordingly, rejection may be withdrawn.

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**CONCLUSION**

The Applicants submit that all of the claims are in condition for allowance, which action is requested. If the Examiner finds that a telephone conference would expedite the prosecution of this application, please telephone the undersigned at the number provided.

The Commissioner is hereby authorized to charge any underpayment of fees associated with this communication, including any necessary fees for extensions of time, or credit any overpayment to Deposit Account No. 50-0815, order number PALO-004.

Respectfully submitted,  
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